



United States Department of Agriculture

May 29, 2019

Charles Smith
Acting Director, Pesticide Re-Evaluation Division (7508P)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW.,
Washington, DC 20460-0001

Re: USDA comments on the Preliminary Ecological (EPA-HQ-OPP-2009-0432-0020) and Human Health (EPA-HQ-OPP-2009-0432-0017) Risk Assessments of Thiodicarb for Registration Review.

Dear Mr. Smith:

The United States Department of Agriculture is pleased to comment on EPA's risk assessments for thiodicarb, published in the Federal Register on April 8, 2019. Thiodicarb, a dimer of methomyl, is a restricted-use N-methyl carbamate insecticide (IRAC chemical sub-group 1A) that acts primarily as an acetylcholinesterase (AChE) inhibitor.

Thiodicarb is only registered for seed treatment use, and it is only co-formulated with imidacloprid in a single registered pesticide product. This imidacloprid+thiodicarb product, Aeris[®], is an important component of IPM programs in cotton and soybean. Aeris[®] confers systemic activity against thrips and is rated as one of the best options for stand-alone thrips control on cotton in the Mid-South. Thiodicarb helps to provide added activity against nematodes and other soil-dwelling pests of soybeans and cotton such as seed maggots, grubs, wireworms, and Lepidopteran pests, such as cutworms and armyworms.

USDA stands ready to work with EPA for questions in providing input for risk assessment refinement and additional information on the characterization of risks, usage, and benefits to address EPA's exposure concerns. Our detailed comments follow. Please let me know if you would like to discuss.

Sincerely,

A handwritten signature in cursive script, reading "Sheryl H. Kunickis", is located below the "Sincerely," text.

Sheryl H. Kunickis, Ph.D.
Director

USDA comments on the Preliminary Ecological (EPA–HQ–OPP–2009-0432-0020) and Human Health (EPA–HQ–OPP–2009-0432-0017) Risk Assessments of Thiodicarb for Registration Review:

Human Health Assessment:

Drinking Water:

USDA notes that EPA applies significant conservatism in the modeling of groundwater (GW) pesticide concentrations. However, the inputs to EPA’s dietary risk assessment for both methomyl and thiodicarb were driven by methomyl—derived from model outputs for multiple foliar applications that resulted in methomyl drinking water concentrations approximately 20 times higher than those predicted for registered seed treatment uses of thiodicarb. It is unclear whether the estimated peak and average groundwater methomyl concentrations projected from thiodicarb use (10.3 ppb and 5.4 ppb, respectively) would be problematic for a dietary safety finding for either chemical. We request that EPA clarify the potential outcome from a combined dietary assessment combining food (methomyl only) and groundwater (thiodicarb seed treatment uses only) and discuss whether mitigation might be proposed for thiodicarb seed treatment uses to address groundwater exposure for methomyl.

USDA understands that EPA policies dictate a high level of conservatism for the screening-level assessment of drinking water concentrations for inclusion in their dietary risk assessments. Given available (albeit limited) usage data (EPA, 2014), the potential target pest pressure differences by region and the high likelihood of crop rotation for cotton and soybean production (including rotation to other crops such as corn and wheat, for example), USDA finds it unlikely that repeated, 30-year perennial usage of thiodicarb seed treatment on the same field would be commonly observed anywhere in the United States.

We further note that EPA’s drinking water assessment for thiodicarb is additionally conservative in assuming that all thiodicarb/methomyl residue is available for movement to ground water. For seed treatments to be effective, a significant proportion of active ingredient must either be taken up by the seed or stay bound to the seed surface. Because thiodicarb is systemic, a significant amount of active ingredient is moved into the seed and the emerging seedling plant to provide efficacy against foliar feeding pests. While quantitative estimates of such systemic plant uptake can be difficult, the well-documented field effectiveness of thiodicarb as a crop protectant provides significant evidence that a large proportion of active ingredient moves to the emerging cotton/soybean plant and thus would be subject to additional degradation pathways above-ground.

USDA requests EPA further consider and characterize a number of factors that would affect modeled water concentrations before any significant mitigations are proposed. Some factors to consider include movement of active ingredient to the emerged plant, the typical soil profiles of areas where cotton and soybeans are most commonly grown in the United States, and typical well depths in these same areas. If mitigation is required for protection of groundwater after consideration of such refinements, USDA requests that risk managers consider geographically specific proposals (such as well setbacks) that would be germane to the specific vulnerable soils of concern only, and not broadly limit the availability of thiodicarb seed treatments to growers on a national basis. USDA stands ready to assist EPA in obtaining information on typical crop

production practices and pesticide usage to address the suggested refinements listed above, and is willing to assist in any other way needed for completion of the registration review process.

USDA notes that dietary risks were not of concern for any surface drinking water scenarios. Further, we agree with EPA's conclusion that only acute exposures are of any potential concern for human health, given the metabolic profile for methomyl (i.e., rapid enzyme recovery within hours obviates the potential for chronic effects) and the lack of potential carcinogenicity concerns for humans.

Occupational Handlers:

USDA notes that occupational handler scenarios for seed treatments were the only scenarios that were specifically addressed for thiodicarb, since other exposure pathways for methomyl are considered protective of thiodicarb exposure. We support EPA's conclusion that no seed treatment handler exposure scenarios were of concern and presume that no occupational risk mitigations will be necessary for handlers of thiodicarb-treated seeds, given the lack of any germane occupational risks of concern identified for methomyl.

Preliminary Ecological Risk Assessment:

USDA appreciates that EPA's preliminary ecological risk assessment for thiodicarb included some helpful risk characterization information for the identified risks of concern, particularly for seed-feeding exposure for terrestrial birds and mammals. USDA agrees with EPA's characterization that widespread problematic exposure from feeding on cotton seeds is highly unlikely, given that cotton seed is high in the natural toxin gossypol, which makes it a non-preferred food item and reduces the likelihood of consumption. We further agree that due to seed size, small passerine bird species are not likely to ingest treated soybean seeds.

Terrestrial Exposure for Birds and Mammals:

Regarding seed treatment exposure, while it is true that a relatively small dietary intake of treated seeds could lead to potential risk concerns, a number of factors combine to limit the potential of such exposure actually occurring on a widespread basis under real-world conditions. EPA's risk assessment already discusses that typical seeding depths and incorporation rates preclude widespread gorge feeding potential for seed consumption, with the exception of inadvertent spills of treated seeds outdoors. USDA agrees that seed incorporation rates are likely to be very high for both soybeans and cotton due to modern planting technology, seed costs (particularly for pesticide-treated or genetically 'traited' seeds) and the yield impacts of inefficient seeding, particularly for cotton.

While complete seed incorporation is not always possible (and thus the risk of exposure is not zero), it is well-known that a number of more preferred food items are often present on the surface of newly planted fields, particularly in fields where no-till or cover cropping practices are employed. Warner et al. (1989) discuss the prevalence of waste seed (i.e., from the prior crop harvest) in fields and estimated typical harvest losses in the range of 6-10%. While it is likely that harvest efficiency has improved since the 1980's-90's, even a conservative estimate of 1% harvest loss (i.e., 1% seed waste from the prior harvest that remains on the soil surface the next

spring) yields an estimate of waste seed availability (for food) that dwarfs the likely number of treated seeds left on the soil surface at planting, as we describe below.

Let us consider a hypothetical estimate of 1% seed loss during harvest, which is likely on the low-end of what would typically be observed in real-world production. Based upon the average national corn yield of 176 bushels per acre (USDA-NASS, 2019), and the typical estimate of 90,000 corn seeds per bushel (Pioneer, undated), a harvest loss of 1.76 bushels per acre would result in loss of approximately 158,000 waste seeds per acre on the soil surface. Similarly for soybeans, based upon the national average soybean yield of 51 bushels per acre (USDA-NASS, 2019) and the typical estimate of 150,000 seeds per bushel (Cargill, undated), a harvest loss of 0.51 bushels per acre would result in loss of approximately 77,000 waste seeds per acre on the soil surface.

For soybeans (the worst-case crop for potential non-target consumption), EPA estimates typical seeding rates at 60,000-240,000 seeds per acre (EPA, 2011). Using EPA's assumption of 99% incorporation, and choosing the upper-bound seeding rate value of 240,000 seeds per acre, a worst-case estimate for potential exposure to treated soybean seeds on the soil surface is 2,400 treated seeds per acre. For no-till soybean fields that are being planted following a prior soybean or corn harvest, the exposure to these 2,400 treated seeds per acre would be in contrast to the availability of approximately 77,000 soybean waste seeds or 160,000 corn waste seeds in a typical field, or about 3% of available seeds as a worst-case scenario. Further driving down this exposure and consumption likelihood would be the presence of other edible litter on the soil surface, including weed seeds/seed banks, emerging weed seedlings, and in some cases, foliage and seeds of cover crops and/or green manure.

Finally, for a comparable alternative to thiodicarb—i.e., aldicarb—EPA's modeled risks to birds and mammals were considerable, including acute exposure potential (EPA, 2017). EPA's published interim registration review decision (EPA, 2017) discussed the both benefits and the low exposure likelihood for widespread risk concerns to birds and mammals from aldicarb. EPA ultimately directed registrants to specify the target incorporation depth on labels and put advisory language on labels regarding soil incorporation, cleanup of spills, and prevention of exposure to birds and mammals. Given that thiodicarb seed treatments provide an alternative to aldicarb on cotton and soybeans, and given that the projected risk concerns for birds and mammals are based upon consumption of treated seeds only, USDA suggests that EPA should consider risk mitigation strategies that are similar with regard to preventing bird and mammal exposure. We further note that limiting the availability of thiodicarb seed treatments for growers of soybeans and cotton may well lead some growers to increase usage of aldicarb to manage thrips and other soil-dwelling pests, which would run counter to EPA's larger strategy for non-target risk reduction in these crops.

Terrestrial Invertebrate (bee) Exposure:

USDA acknowledges that thiodicarb, as an N-methyl carbamate insecticide, is likely to be acutely toxic to bees. However, because thiodicarb is only registered for seed treatment use on cotton and soybeans, the expected systemic exposure in pollen and nectar is likely to be very low, given the significant growth 'dilution' of likely active ingredient concentration in the emerged plant by the time it reaches a blooming stage. For cotton and soybeans, in particular, bloom is most likely to occur long after bio-active concentrations of thiodicarb or methomyl

remain present in actively growing plant tissue. While quantitative estimates can be difficult, it is notable that the active period of efficacy against pests feeding directly on the plant is generally gone within several weeks of crop emergence.

Aquatic Invertebrate Exposure:

USDA notes that modeled impacts to aquatic invertebrates are to be expected for an acutely toxic, broad-spectrum insecticide. We appreciate that EPA's assessment took typical seeding depth into account in modeling surface water EECs. Added characterization around the comparison of NOAEC and LOAEC values could marginally refine the chronic exceedance estimate for aquatic invertebrates. We further suggest that because thiodicarb is only used as a co-formulation partner with imidacloprid, the modeled aquatic exposure values, risk estimates, risk characterizations, and associated proposed mitigations for imidacloprid on treated seed uses should be considered when evaluating the relative risk estimates and any potential proposed risk management strategies for thiodicarb.

Thiodicarb Usage and Benefits:

Because thiodicarb is only registered for seed treatment use, only limited pesticide usage data is available to USDA. We note that EPA's Screening-level usage analysis (EPA, 2014) indicated that between 5 and 10 percent of cotton was planted with thiodicarb treated seed over the reporting period of 2005-2014. We also acknowledge that thiodicarb (as part of the combination product Aeris[®]) is commonly recommended by Mid-South extension experts as one of the best stand-alone seed treatment options for thrips control on cotton (Stalcup, 2018).

While usage data are not readily available for soybeans, we point out that thiodicarb expands the spectrum of seed-protection activity conferred by imidacloprid and provides efficacy against soil pests such as grubs, wireworms, seed maggots, etc. in both cotton and soybeans. This efficacy is particularly important in the Mid-South, where soybeans are often planted early in the season into soils that have been cover-cropped, and thus have higher populations of soil-dwelling insect pests.

References:

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- Stalcup, L., 2018. Insecticide Seed Treatments Help Make a Stand, But Some May Need a Boost From Foliar Insecticides. Delta Farm Press. <https://www.farmprogress.com/insecticide/insecticide-seed-treatments-help-make-stand-some-may-need-boost-foliar-insecticides>. Accessed May 28, 2019.
- USDA-NASS, 2019. USDA Crop Production 2018 Summary. https://www.nass.usda.gov/Publications/Todays_Reports/reports/cropan19.pdf. Accessed May 28, 2019.

Mention of a trade name or brand name does not constitute endorsement or recommendation by USDA over similar products or vendors.